

REMARKS

The Applicants thank the Examiner for her time and courtesy during the personal interview on April 20, 2005.

Upon entry of the amendment, claims 1, 4-7, 19-20, 80, 84-85, 91, 95 and 97 will be pending in the case. Changes have been made to correct obvious typographical errors in the specification. Applicants submit that the amendments contain no new matter.

I. Rejections under 35 USC 102

Claims 1, 5, 13, 91 and 95 are rejected under 35 USC 102 for anticipation by Yiv (USP 5,707,648); or WO95/14037. The Examiner alleges that the broad teachings of Yiv teach the invention of the instant application. The Applicants have amended claim 1 to recite specific combinations of CDCA or UDCA with a fatty acid and an oligonucleotide as taught in the instant application, specifically in Example 11 and Table 18. The bioavailability of the oligonucleotide in the emulsions was found to be enhanced as compared to the bioavailability of oligonucleotide delivered in a control solution lacking any penetration enhancers, as defined on pg 71, ln 24-25. The language of the claim is supported on page 5, lines 3-6. There are no teachings in Yiv regarding the specific formulation of the claims, or the enhancement of bioavailability produced by the formulation. Therefore, claim 1 is not anticipated by the teachings of Yiv. Moreover, as the remaining claims in the rejection are dependent on the non-anticipated claim 1, they are also not anticipated by the reference and are therefore novel.

II. Rejections under 35 USC 103

The Examiner has rejected claims 1, 4-7, 13, 19-20, 80, 84-85, 91 and 95 for obviousness under 103(a) as being unpatentable over Kawai in view of Yiv, Bennett (USP 5,514,788) and Neilsen.

The Examiner alleges that the broad teachings of Kawai combined with broad teachings of the above named references make obvious the claims of the instant invention. Applicants respectfully disagree. Each of the references cited by the Examiner provide only broad teachings regarding formulations. There is no motivation to select the specific formulations claimed in the instant invention as required for a proper obviousness rejection. Applicants submit that the small number of species claimed would not be obvious in view of the teachings of large genres of penetration enhancers in the prior art. Moreover, the enhanced bioavailability of oligonucleotides

that is produced by the formulations of the instant invention is not obvious in view of the references cited. Applicants submit that claim 1 is clearly distinguished from the prior art references. As the remaining claims in the rejection are all dependent on claim 1, either directly or indirectly, they are also not obvious in view of the references cited.

FEES

Applicants hereby authorize the Commissioner for Patents to charge \$510.00 to Deposit Account 50-0252, referencing case number ISIS-3510, the fee for a three (3) month extension in time for reply. It is believed that no additional fee is due with this response. However, if a fee is due, the Commissioner is hereby authorized to charge the Deposit Account listed above, referencing the case number listed.

CONCLUSIONS

Applicants submit that in view of the forgoing amendments and remarks that the application is now in proper form for allowance. However, if the Examiner believes that there are outstanding issues remaining in the case, the Examiner is encouraged to call the Agent for Applicant listed below to discuss the matter.

Date: Sept 16, 2005

Respectfully submitted,



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